

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION**

PAMELA BUTLER, et al.,	)	
	)	
<i>Plaintiffs,</i>	)	No. 4:18-cv-01701-AGF
v.	)	
	)	
MALLINCKRODT, INC., et al.	)	Lead Case
	)	
<i>Defendants.</i>	)	

**MALLINCKRODT’S MEMORANDUM IN  
SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT**

Defendant Mallinckrodt, LLC (“Mallinckrodt”), pursuant to Fed. R. Civ. P. 56 and E.D.Mo. L.R. 4.01(A) hereby submits its Memorandum in Support of its Motion for Summary Judgment.

**I. THE BASIS FOR MALLINCKRODT’S MOTION, IN BRIEF.**

Plaintiffs’ only cause of action, a claim under the Price-Anderson Act (“PAA”), 42 U.S.C. § 2011 *et seq.* (Doc. #1), fails as a matter of law because Plaintiffs have no evidence of the following essential elements of their claim (1) radiation caused their claimed illnesses, (2) an exposure above natural background, and (3) breach of a federal radiation safety regulation. Because Plaintiffs bear the burden of proof on each of these elements, a finding in favor of Mallinckrodt on any one of these independent grounds is dispositive. This motion is the inevitable result of the Court’s comprehensive order on Mallinckrodt’s and Cotter’s joint motions to exclude Plaintiffs’ experts. Without the excluded expert opinions, the Plaintiffs have no evidence to support their claims. As such, summary judgment in Mallinckrodt’s favor is proper.

## **II. THE FACTS.**

### **A. Historical Background.**

Mallinckrodt processed uranium under contracts with the United States Government, through the Manhattan Engineer District (“MED”) and Atomic Energy Commission (“AEC”). SOF ¶ 37. In 1946, the MED acquired a 21-acre site just north of the St. Louis Airport now known as “SLAPS” for storage of radioactive waste. SOF ¶ 38. The MED, and later its successor the AEC, maintained SLAPS for storage of radioactive waste product from approximately 1946 until July 1953. SOF ¶ 39.

From 1953 until 1966, the AEC retained Mallinckrodt to maintain the government-owned SLAPS. SOF ¶ 42. Mallinckrodt performed all of its activities at SLAPS pursuant to contracts with the U.S. Government, and the MED, and later AEC, provided oversight and supervision of Mallinckrodt’s activities. SOF ¶ 43. The AEC required its contractors, including Mallinckrodt, to comply with its safety standards. SOF ¶ 46. Further, Mallinckrodt’s contracts with the MED and AEC required that Mallinckrodt perform its work in accordance with the AEC’s health and safety regulations and requirements. SOF ¶ 56. Mallinckrodt’s operations at SLAPS ended on February 14, 1966. SOF ¶ 42.

### **B. Plaintiffs’ Claims and The Exclusion of Their Experts.**

Plaintiffs are four individuals alleging their four dissimilar illnesses were caused by exposure to radiation from defendants’ operations. ECF No. 1, ¶ 24.<sup>1</sup> Specifically, Plaintiffs allege exposure to radioactive isotopes Radium-222, Thorium-230 and Uranium-238. ECF No. 104 at 1. Pamela Butler alleges that she lived near Coldwater Creek from 1983 to 1993 and that

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<sup>1</sup> The plaintiffs’ four nearly identical Complaints were filed as Doc. #1 in their individual cases: Pamela Butler, 4:18-cv-01701; Kenneth Koterba, 4:18-cv-01702; Anthony Hines, 4:18-cv-01703; and Emery Wallick, 4:18-cv-01704. All four Complaints are identical with the exception of paragraph 24, which provides biographical information for the respective plaintiff.

she was diagnosed with breast cancer in 2016. SOF ¶ 2-3. Kenneth Koterba alleges he has lived near Coldwater Creek since 1964 and that he was subsequently diagnosed with an intra-axial brainstem tumor in 2015. SOF ¶ 4-5. Anthony Hines alleges that he lived near Coldwater Creek from 1962 to 1974 and again from 1976 to 1982. SOF ¶ 6. He alleges he was diagnosed with mantle cell lymphoma in 2015. SOF ¶ 7. Finally, Emery Walick alleges he lived near Coldwater Creek from 1990 to 1997, 2008 to 2010 and 2012 to 2014. SOF ¶ 8. He alleges he was diagnosed with a medulloblastoma in 2014. SOF ¶ 9.

On these allegations, Plaintiffs assert a single “cause of action pursuant to the Price Anderson Act” known as the “public liability action”, 42 U.S.C. § 2011 *et seq.* ECF No. 1, p. 20. Plaintiffs filed their Complaints on October 5, 2018. SOF ¶ 1. The Court consolidated the cases into *McClurg*<sup>2</sup> on November 13, 2018 pursuant to the Eastern District of Missouri’s Administrative Order Regarding Radionuclide Exposure Claims against Mallinckrodt, LLC and/or Cotter Corporation (N.S.L). ECF Nos. 63-11, 63-10. They were also subject to the Court’s Case Management Order No. 14 for Future Consolidated Cases Filed Against Cotter Corporation (N.S.L.) and/or Mallinckrodt, LLC (“CMO 14”). ECF No. 63-9. Seven months later, the Court entered Case Management Order No. 1 applicable to these cases. SOF ¶ 13.

On November 12, 2020, the Court severed *Butler* from *McClurg*. ECF No. 32. On August 18, 2021, Defendants filed Joint Motions to Exclude Plaintiffs’ Experts. ECF Nos. 47, 49 and 51. The Court heard argument on those motions on March 10, 2022. ECF No. 90. On March 31, 2022, the Court issued an order partially granting Defendants’ motions to exclude Plaintiffs’ experts. ECF No. 104. That order excluded Plaintiffs’ dose reconstruction expert

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<sup>2</sup>“*McClurg*” refers to the original consolidated action for these and similar radiation cases which were originally consolidated in to this court under lead Case No. 4:12-cv-00361-AGF, *Scott D. McClurg, et al. v. Mallinckrodt, Inc., et al.*, In the United States District Court for the Eastern District of Missouri.

(Clark) entirely. *Id.* It also limited the testimony of Plaintiffs' causation expert (Hu) and their standard of care expert (Wells). *Id.* Without the excluded expert opinion evidence, the Plaintiffs' cannot satisfy their burden on several elements of their claims as a matter of law. Without Dr. Clark, the Plaintiffs cannot establish any exposure. Without Dr. Hu, the Plaintiffs cannot establish causation. Without Dr. Wells, the Plaintiffs cannot establish Mallinckrodt breached its standard of care.

### **III. SUMMARY JUDGMENT STANDARD.**

Summary judgment must be granted “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A party opposing a motion for summary judgment must show a fact is genuinely disputed by citing to particular materials in the record, by showing that the materials cited by the moving party do not establish the absence of a genuine dispute, or by establishing that the adverse party cannot produce admissible evidence to support the fact. Fed. R. Civ. P. 56(c)(1). If a claim involves complex or technical information or is highly scientific it requires expert testimony. *McMahon v. Robert Bosch Tool Corp.*, 5 F.4<sup>th</sup> 900, 905 (8th Cir. 2021); *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000) (Requiring expert testimony under Missouri law when the injury is a “sophisticated” one that requires highly scientific techniques for diagnosis); *McMunn v. Babcock & Wilcox Power Gen. Grp., Inc.*, 869 F.3d 246, 269 (3rd Cir. 2017) (Requiring expert testimony for standard of care and causation to prove a claim under the Act); *see also Menz v. New Holland N. Am., Inc.*, 507 F.3d 1107, 1111 (8th Cir. 2007) (expert testimony is necessary “where the lay jury does not possess the experience or knowledge of the subject matter sufficient to enable them to reach an intelligent opinion without help” under Missouri law (brackets and quotations omitted)); *Pro Serv. Auto.*,

*LLC v. Lenan Corp.*, 469 F.3d 1210, 1214 (8th Cir. 2006) (same). If an expert designated on an element for which expert testimony is required is excluded, summary judgment is proper. *Id.*

#### **IV. ARGUMENTS & AUTHORITIES.**

To prevail on a PAA claim, a plaintiff must establish that: (1) the defendant breached the levels permitted by the federal regulations in effect at the time of the conduct (i.e., a breach of the federal standard of care); (2) the plaintiff was exposed to this radiation; (3) the plaintiff has injuries; and (4) radiation was the cause of plaintiff's injuries. *See In re TMI Litig.*, 67 F.3d 1103, 1119 (3d Cir. 1995), *cert. denied*, 516 U.S. 1154 (1996) ("*TMI II*"); *In re TMI Litig.*, 193 F.3d 613, 659 (3d Cir. 1999) ("*TMI III*") (agreeing with these elements); *McClurg v. MI Holdings, Inc.*, 933 F. Supp. 2d 1179, 1187 (E.D. Mo. 2013) (same); *McClurg v. Mallinckrodt, Inc.*, No. 4:12-CV-00361-AGF, 2017 WL 2929444, at \*6 (E.D. Mo. July 7, 2017) (same). As part of element two, exposure, plaintiffs must show "they have been exposed to a greater extent than anyone else, i.e., that their exposure levels exceed the normal background level." *Id.*

Plaintiffs cannot meet their burden as to elements (1), (2) and (4). Plaintiffs cannot establish that (1) Mallinckrodt breached any applicable federal regulations; (2) Plaintiffs were exposed to radiation, nor in an amount greater than anyone else; or (4) radiation from Mallinckrodt's operations caused their diseases.

##### **A. Plaintiffs have no evidence that radiation from Mallinckrodt's operations caused their diseases.**

Causation in a public liability action is determined under state law. *McMunn v. Babcock & Wilcox Power Gen. Grp., Inc.*, 869 F.3d 246, 269 (3rd Cir. 2017). To prove causation in a toxic tort case in Missouri, a plaintiff must show both that the alleged toxin is capable of causing injuries like that suffered by the plaintiff in human beings subjected to the same level of exposure as the plaintiff, and that the toxin was the cause of the plaintiff's injury. *Bonner v. ISP*

*Tech, Inc.*, 259 F.3d. 924, 928 (8th Cir. 2001). Expert testimony is required to make this showing. *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000) (Expert testimony required for “sophisticated” injuries in Missouri); *Junk v. Terminix Intern. Co.*, 628 F.3d 439, 450 (8th Cir., 2010) (“To prevail in a toxic tort case, the plaintiff must show both general and specific causation” and “in proving both types of causation, “expert medical and toxicological testimony is unquestionably required to assist the jury””); CMO No. 14 at 10 (Requiring expert opinion on specific causation.) Plaintiffs designated Dr. Hu for purposes of meeting this standard and he admittedly relied exclusively on Dr. Clark’s dose opinions to opine that each Plaintiffs’ exposure to uranium, thorium and radium from Coldwater Creek was sufficient to cause their cancers. SOF ¶ 22.

The Court excluded Dr. Clark’s opinions in their entirety. The Court also excluded Dr. Hu’s specific causation opinions that radiation caused or contributed to Plaintiffs’ cancers. ECF No. 104 at 29. As a result, Plaintiffs cannot meet their burden on specific causation because there is no evidence to support it. Under Price-Anderson, Eighth Circuit, and Missouri law, summary judgment is proper when there is no expert testimony for purposes of establishing causation in a complex causation case like this one. *In re TMI Litig.*, 193 F.3d at 716 (“The District Court’s grant of summary judgment in favor of the defendants was the inevitable result of its exclusion of the testimony of the Trial Plaintiffs’ dose exposure witnesses.”); *McMunn*, 869 F.3d at 274 (Affirming summary judgment because plaintiffs’ experts failed to show sufficient exposure to radiation to cause their alleged cancers.); *Junk*, 628 F.3d at 449 (8th Cir. 2010); *Turner v. Iowa Fire Equipment Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000) (Affirming district court’s grant of summary judgment on causation under Missouri law after plaintiffs’ causation expert was excluded.)

**B. Plaintiffs have no evidence that they were exposed to a greater extent than anyone else.**

In addition, Plaintiffs cannot satisfy their exposure element, which requires the Plaintiffs show they have been exposed to radiation released by Mallinckrodt in an amount above everyone else. *In re TMI Litig.*, 193 F.3d at 659. This element is unique for the particular toxin at issue in this case, ionizing radiation, because it is naturally occurring and everyone is exposed to it at all times, hence the established term “natural background.”<sup>3</sup> Here, Plaintiffs wholly failed to consider their exposure in light of natural background levels and the Court excluded the individual dose reconstruction they attempted to use for doing so because it was not reliable. ECF No. 104, *Mem. and Ord.* at 15. As a result, Plaintiffs have no evidence of any exposure, and certainly not an exposure which satisfies their burden for this element.

As a brief reminder, Plaintiffs attempted to meet this threshold by comparing their failed individual dose reconstructions to a fictitious background level, which was also excluded. ECF No. 50 at 17-18. They did not use 360 *millirem* for natural background, which is the standard in this field and is what their principal source, the Agency for Toxic Substances and Disease Registry (ATSDR) Public Health Assessment Evaluation of Community Exposure Related to Coldwater Creek, relied on. ECF No. 104 at 35 citing, *In re TMI Litig.*, 193 F.3d at 644 n.50 (noting that, while “[n]atural background radiation levels vary widely throughout the world . . . it has been estimated that the average annual dose in the United States from natural background radiation is . . . around 3 mSv or 300 mrem”); *McMunn*, 869 F.3d at 279 (McKee, J., concurring) (“[T]he typical average individual exposure in the United States from natural background sources is about 300 millirems per year.”) (citing U.S. Nuclear Regulatory Comm’n,

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<sup>3</sup> In *McMunn*, the Third Circuit held this is merely a threshold and not a substitute for causation. *McMunn*, 869 F.3d at 273.

*Background radiation*, <https://www.nrc.gov/reading-rm/basicref/glossary/background-radiation.html>.).

The Plaintiffs did not utilize the scientifically accepted natural background in their comparison because their exposures were tiny fractions of natural background. ECF No. 52, Joint Mot. to Exclude Dr. Hu at 20-21. The comparison to natural background is irrelevant at this point because Plaintiffs have no evidence of exposure to compare to natural background, but even if Dr. Clark's doses had survived, they could not satisfy this element. *Mem. and Ord.*, at 35 (If Clark had used natural background, Clark "would have found that each Plaintiff's exposure was in fact lower than the background level.")

Because the Plaintiffs have completely failed to meet their burden on this element, summary judgment is also required on this independent ground.

**C. Plaintiffs have no evidence Mallinckrodt violated a federal regulation and Mallinckrodt is not subject to strict liability.**

In addition to showing radiation caused their cancers and an exposure above anyone else, Plaintiffs bear the burden to introduce admissible expert testimony that Mallinckrodt breached the standard of care it owed Plaintiffs. *McMunn*, 869 F.3d at 267-68. In a public liability action, that standard of care is set by the applicable federal regulations in effect at the time of the alleged breach and requires the plaintiff to show an exposure that exceeded those federal regulations. *In re TMI Litig.* 67 F.3d 1105-06; *McClurg v. MI Holdings, Inc.*, 933 F.Supp.2d 1179, 1887 (E.D.Mo., 2013) (citing *Cook v. Rockwell Int'l Corp.*, 618 F.3d 1127 (10th Cir. 2010)). Here, Plaintiffs have presented no evidence of the federal regulations applicable to Mallinckrodt or any breach of them.<sup>4</sup> Plaintiffs' only expert to opine on this issue was Dr. Wells and the Court

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<sup>4</sup> The only evidence before the Court on the federal regulations applicable to Mallinckrodt has been put forth by Mallinckrodt in this Motion and a prior motion. Dr. Wells testified that he did



excluded his opinions on these topics. *Mem. and Ord.* at 30. Accordingly, summary judgment is also appropriate based on Plaintiffs' failure to carry their burden on this required element of their claim.

In their *Daubert* briefing, Plaintiffs offered an alternate theory that Mallinckrodt should be subject to strict liability. Mallinckrodt is not subject to strict liability under the PAA.<sup>5</sup> Plaintiffs support their argument by claiming there were no federal regulations applicable to Mallinckrodt prior to 1957, which is simply incorrect.

When the AEC began operations in 1947, and throughout its existence, it adopted radiation safety standards developed by the National Bureau of Standards ("NBS") and National Committee on Radiation Protection and Measurement ("NCRP") and required its contractors, including Mallinckrodt, to comply with them.<sup>6</sup> SOF ¶ 46-47. In 1949, the NBS published Handbook 42, *Safe Handling of Radioactive Isotopes*. SOF ¶ 48. Handbook 42 imposed a limit on radiation and radioactive materials that may be present in unrestricted areas from a Government facility, like SLAPS. SOF ¶ 49. In anticipation of the publication of Handbook 42, the AEC issued Bulletin GM-133 on June 10, 1949. SOF ¶ 50. This Bulletin specified codes

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not review the applicability of any other regulations beyond 10 C.F.R. § 20 and Plaintiffs otherwise have no evidence of applicable regulations.

<sup>5</sup> Plaintiffs attempt to evade the repercussions of their experts' failures through strict liability would not prevent entry of summary judgment for the other reasons stated herein and Mallinckrodt would still be entitled to certain defenses such as the public duty exception and the government contractor defense—arguments that Mallinckrodt reserves but are not the subject of this Motion.

<sup>6</sup> Mallinckrodt previously briefed the Court on the standard of care issues, ECF No. 586, "Mallinckrodt's Motion for Ruling on Common Issue of Applicable Standard of Care and Memorandum In Support." The Court ultimately denied Mallinckrodt's motion as premature on February 12, 2018. *McClurg*, ECF No. 677. The facts needed to resolve this issue are contained in the present motion, but additional context and explanation is provided in Mallinckrodt's prior standard of care motion and reply, ECF No. 660, which Mallinckrodt incorporates by reference.

and standards applicable to AEC personnel and AEC contractors. *Id.* Regarding radiation safety, the Bulletin mandated compliance with Handbook 42 and another NBS publication, *Permissible External Dose*. SOF ¶ 51.

The Atomic Energy Act of 1954 specifically authorized the AEC “to govern any activity authorized pursuant to this chapter, including standards and restrictions governing the design, location, and operation of facilities used in the conduct of such activity, in order to protect health and to minimize danger to life or property.” 42 U.S.C. §§ 2201(i)(3) (1954).

Starting in 1957, the AEC issued Manual Chapters, rather than the Bulletins. SOF ¶ 53. The Manual Chapters expressly adopted specific NBS Handbooks and successive versions of these Manual Chapters were in effect until May 5, 1980. SOF ¶ 54. Despite the differences in how contractors and licensees are bound to these standards, the standards themselves are in substantial agreement with each other. SOF ¶ 55.

The AEC publications, bulletins and manual chapters establish the regulations referred to in element one of a public liability action under the PAA, rendering strict liability improper. *Boggs v. Divested Atomic Corporation*, No. 2:90cv840, 2008 WL 11336114 (S.D. Ohio, June 18, 2008). In *Boggs*, the Court determined that a government contractor should not be strictly liable precisely because of these federal regulations, explaining:

[The AEC] had adopted federal regulations governing radioactive emissions during the years before 1958, where it exercised its administrative discretion and incorporated by reference the codes governing such emissions promulgated by the International Commission for Radiological Protection and National Committee on Radiation Protection and published by the National Bureau of Standards, into AEC Bulletins GM-133 and GM-SFP-3.

*Id.* The *Boggs* Court rejected the Ninth Circuit’s strict liability reasoning in *Hanford*, in part, because the *Hanford* court, like Plaintiffs’ expert Dr. Wells, “did not cite or discuss AEC Bulletin GM-133 and/or AEC Bulletin GM-SFP-3,” which the *Boggs* court held “constituted

federal regulatory requirements.” *Id.* at \*4 citing *In re Hanford Nuclear Reservation Litigation*, 534 F.3d 986, (9th Cir. 2007).

Mallinckrodt’s operations at SLAPS (and elsewhere) were subject to federal regulations and Plaintiffs’ were required to introduce expert testimony to establish a breach of those regulations by Mallinckrodt. *McMunn*, 869 F.3d at 267-68. All of the opinions of Dr. Wells on this subject have been stricken by the Court. Accordingly, Plaintiffs have no evidence of any breach under the applicable (or any) standard and summary judgment is proper.

**V. CONCLUSION.**

For the reasons stated above, Mallinckrodt request that the Court enter an Order granting summary judgment against Plaintiffs and in favor of Mallinckrodt.

Dated: May 6, 2022

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 6th day of May, 2022, I served the above to the following counsel of record via the Court's electronic filing system.

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